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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,581	10/23/2001	John H. Stevens	HRT-287	4692

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EXAMINER

ISABELLA, DAVID J

ART UNIT PAPER NUMBER

3738

DATE MAILED: 10/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/047,581

Applicant(s)

STEVENS, JOHN H.

Examiner

DAVID J ISABELLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15-44 is/are pending in the application.
- 4a) Of the above claim(s) 33-41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-32, 42-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Status of the Claims

Claims 1-14 have been cancelled and claims 15-44 remain in this application. As per Applicants note, the prior filed set of claims contained two claims that were numbered 32. As a result, Applicants have amended the affected claims to renumber the second claim 32 and the subsequent claims as claims 33-38. Additionally, Applicant added claims 39-44 to more clearly define the invention, especially that subject matter depicted in Figures 11, 13a, 14a and 15a.

Claims 33-38 were previously withdrawn from consideration as being distinct and drawn to a non-elected invention. Applicant respectfully traversed this action. Applicant argues that independent claim 33 contains elements including: a valve and a mounting ring-that are similar to those in originally filed claims 7 and 8. However, the dependent claims include additional elements, such as a catheter and a guide wire, and have a claim scope that differs from the claim scope in claims 15-31. The combination of claims 33-40 differ from the subcombination of claim 15. As a result, applicants request for reinstatement of the withdrawn claims is not persuasive and claims 33-40 stand withdrawn as being directed to an invention that is independent or distinct from the invention as originally claimed.

Currently, claims 15-32,42-44 are pending for immediate action.

Election/Restrictions

Submitted claims 33-40 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the original scope

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of the elected invention is directed to a valve and the added claims 33-40 are directed to a valve device which includes a mounting ring and a valve in combination with a catheter and guidewire. Note, the scope of the valve of claim 33 is not commensurate with the scope of the valve of claims 15-32.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 33-40 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-32, 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen et al (5840081) in view of Lazarus (5104399) or Sakura, Jr (4214587)

The device of Peale may be inserted into the natural conduit but must rely on strict adherence to sizing diameters to match the diameter of the natural conduit. Sakura, Jr allows for direct attachment of the valve of Peale to the natural conduit without strict

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adherence to matching diameters thus alleviating the need for frictional fit. Moreover the spring of Sakura, Jr allows the attaching vessel to pulsate in a fashion similar to that of the natural conduit. It would have been obvious to one with ordinary skill in the art to attach the vessel of Peale to the natural conduit via a compressible spring member as shown by Sakura, Jr. With respect to claim 29, clearly the spring is capable of being balloon expandable as broadly claimed..

The device of Andersen et al includes a valve for implantation comprising a flexible sleeve having proximal and distal ends; and at least one cusp configured to permit blood flow through the sleeve in a single direction and one ring attached to the sleeve. While the device of Andersen et al may be inserted into the natural conduit, the device is sutured to the adjacent tissues of the natural conduit. .Lazarus teaches the combination of tubular vasucular device comprising a cylindrical radially resilient spring formed with outwardly extending fastening elements for attaching a vessel to a natural conduit. Lazarus allows for direct attachment of the sleeve/valve to the natural conduit without strict adherence to matching diameters and the complexities surrounding the use of sutures. Moreover the spring/fastening combination of Lazarus will allows the attaching vessel to pulsate in a fashion similar to that of the natural conduit. It would have been obvious to one with ordinary skill in the art to attach the sleeve/valve of Andersen et al to the natural conduit via a compressible spring member as shown by Lazarus. With respect to claim 29, Lazarus teaches the use of a balloon to expand the radially resilient spring/fastening elements to attach the sleeve to the natural conduit.

Likewise, Sakura, Jr teaches a anastomosis device comprising a cylindrical radially resilient spring formed with outwardly extending fasting elements for attaching a vessel to a natural conduit. It would have been obvious to one with ordinary skill in the art to attach the sleeve/valve of Andersen et al to the natural conduit via a compressible spring member as shown by Sakura, Jr.

Claims 16,17,18,19,20, see figures 11 and 12 of Andersen, et al and corresponding columns 6 & 7 of the specification.

Claim 21, see mounting ring located at the proximal and distal ends of the sleeve of Lazarus.

Claim 22, see combination of Sakura, Jr.

Claims 23-28, see Andersen, et al as modified by either of Lazarus or Sakura, Jr.

Claim 29, see expandable combination as taught by Andersen, et al and Lazarus.


Claims 30-32, see column 6, lines 55+ of Andersen,et al.

Claims 42-44, see fasteners of Lazarus.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J ISABELLA whose telephone number is 703-308-3060. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 703-308-2111. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI
October 25, 2004